

Docket No.: 1422-0655PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Makoto ISHIKAWA, et al.

Conf.: 7260

Application No.: 10/518,926

Art Unit: 1796

Filed: December 23, 2004

Examiner: Timothy KUGEL

For: OIL-IN-WATER EMULSION COMPOSITION

APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

(i) Real party in interest.

The real parties in interest in this appeal are TAIYO KAGAKU CO., LTD. and KABUSHIKI KAISHA YAKULT HONSHA, joint assignees of the subject application.

(ii) Related appeals and interferences.

There are no related appeals or interferences.

(iii) Status of claims.

Claims 1-4 are pending and under examination. Claims 5-10 have been cancelled. This is an appeal from the Final Rejection of claims 1-4.

(iv) Status of amendments.

No amendment was filed subsequent to the final rejection (see Final Office Action of September 16, 2008).

(v) Summary of claimed subject matter

In accordance with the present invention, an oil-in-water emulsion composition is provided. Specification, page 4, lines 19-20. In the oil-in-water emulsion of the present invention, one component is a fat or oil composition comprising a polyvalent unsaturated fatty acid component (specification, page 7, lines 19-25) and sucrose acetate isobutyrate (specification, page 9, lines 20-23), wherein the amount of the sucrose acetate isobutyrate is from 25 to 300 parts by weight, based on 100 parts by weight of the polyvalent unsaturated fatty acid component (specification, page 10, lines 4-9). In the oil-in-water emulsion of the present invention, another component is a polyglycerol fatty acid ester. Specification, page 10, lines 16-25. The composition of the present invention avoids unpleasant odor and taste. Specification, page 4, lines 3-9.

(vi) Grounds of rejection to be reviewed on appeal.

The sole ground of rejection to be review in this appeal is the rejection of claims 1-4 under 35 U.S.C. § 103(a) as being unpatentable over US 6,193,986 B1 (Sakurada) in view of US 4,379,755 (Yamada) and WO 01/58279 (Takahashi).

*(vii) Argument*CLAIMS 1-4: NO PRIMA FACIE CASE OF OBVIOUSNESS

Sakurada discloses a water-in-oil emulsion. See column 2, line 37; column 7, lines 32-42 (“mixing the aqueous phase with an oil phase ... to finally obtain a W/O-type emulsion”); and Sakurada claim 11. The Sakurada water-in-oil emulsions are distinct from the oil-in-water emulsions of the present invention. As the Examiner recognizes, Sakurada fails to teach or suggest an oil-in-water emulsion. See the Final Office Action of September 16, 2008, page 4, lines 10-11.

Yamada does not remedy the deficiencies of the Sakurada reference. The oil-free gelatinizing agent of Yamada contains (a) hydrophilic sucrose fatty acid ester and (b) hydrophilic liquid polyhydric alcohol. In contrast, the sucrose acetate isobutyrate employed in the present invention is lipophilic, not hydrophilic. In lines 37-41 of column 1, Yamada refers to disadvantages such as non-homogeneity and poor feel arising from the use of lipophilic sucrose esters. The Yamada teaching of using hydrophilic sucrose fatty acid esters teaches away from the use of lipophilic sucrose esters as in the present invention. This express description in the Yamada reference of disadvantages arising from the use of lipophilic sucrose esters is material to the validity of the rejection of Applicants’ claims under 35 U.S.C. § 103. See *In re Graselli*, 713 F.2d 731 at 743, 218 USQ 769 at 779 (Fed. Cir. 1983). In this regard, however, the Examiner says only that “the teaching of hydrophilic sucrose fatty acid esters does not rise to the level of ‘teaching away’.” The Examiner fails to explain why a person of ordinary skill in the art would disregard the Yamada teachings concerning the disadvantages of employing lipophilic sucrose esters (such as the sucrose acetate isobutyrate required by Appellants’ claims). No evidence has been set forth by the Examiner.

As the Examiner recognizes, neither Sakurada nor Yamada teaches or suggests sucrose acetate isobutyrate as an emulsifying agent. See Final Office Action, page 4, last paragraph. The Examiner alleges that Takahashi discloses that sucrose acetate isobutyrate is an equivalent emulsifying agent to the sucrose fatty acid esters taught by Sakurada, citing paragraph [0029] of Sakurada. Appellants respectfully disagree. Takahashi merely lists many different types of

emulsifiers that can be used as alternatives or in combination *in the Takahashi technology*. The Takahashi reference teaches nothing at all about equivalence of emulsifiers in the Ishikawa technology (that is, Appellants' technology).

The Examiner contends that “one of ordinary skill in the art at the time the invention was made would have understood the teaching of Takahashi to be that the emulsifiers where [sic, were] functionally equivalent in emulsifying regardless of the technology used.” Appellants respectfully disagree. Takahashi relates to a method for producing whipped cream. Takahashi fails to suggest the emulsification and stabilization of polyunsaturated fatty acids, which are features of the present invention. Moreover, in the examples of Takahashi, plural emulsifiers are used. Accordingly, a person of ordinary skill in the art would not anticipate the effects of the present invention – that is, the improvement of stability for storage of polyunsaturated fatty acids by using only the specific emulsifier sucrose acetate isobutyrate and claimed amount thereof – from the Takahashi disclosure. It is axiomatic in the art that emulsifiers are not functionally equivalent to one another. This is emphasized by comparing the test results of Appellants' Example 1 with Follow-Up Examples A-D in the Ishikawa Declaration¹.

Neither Sakurada nor Yamada teaches or suggests sucrose acetate isobutyrate as an emulsifying agent. Appellants respectfully disagree with the Examiner's assertion that Takahashi discloses that sucrose acetate isobutyrate is an equivalent emulsifying agent to the sucrose fatty acid esters taught by Sakurada. Again, Takahashi merely lists many different types of emulsifiers that can be used as alternatives or in combination *in the Takahashi technology*. The Examiner states only that “the rationale to combine is found in the prior art cited and in light of established precedence.” Appellants respectfully submit that the Examiner's position on this point should not be sustained, as this is equivalent to saying the skilled artisan had the capability to make the asserted combination.

The Examiner has not established, either by scientific explanation or by evidence, that, *prima facie*, one of ordinary skill in this art, following the combined teachings of the applied references, would have been motivated, or have the proper rationale or reasonable expectation of success, to prepare an oil-in-water emulsion composition comprising a polyglycerol fatty acid

¹ The Ishikawa Declaration under 37 CFR 1.132 was filed January 31, 2008.

ester and a fat or oil composition that includes a polyvalent unsaturated fatty acid component and sucrose acetate isobutyrate, wherein the amount of the sucrose acetate isobutyrate is set to be from 25 to 300 parts by weight, based on 100 parts by weight of the polyvalent unsaturated fatty acid component. *See, e.g., KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007) (it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does); *In re Warner*, 379 F.2d 1011, 1016 (CCPA 1967) (where the invention sought to be patented resides in a combination of old elements, the proper inquiry is whether bringing them together was obvious and not whether one of ordinary skill having the invention before him would find it obvious though hindsight to construct the invention from elements of the prior art); *cf. Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993), citing *Ex parte Gerlach* 212 USPQ 471 (Bd. App. 1980) (“At best, the examiner’s comments regarding obviousness amount to an assertion that one of ordinary skill in the relevant art would have been able to arrive at appellant’s invention because he had the necessary skills to carry out the requisite process steps. This is an inappropriate standard for obviousness That which is within the capabilities of one skilled in the art is not synonymous with obviousness.”).

UNEXPECTED BENEFICIAL PROPERTIES

Graham v. John Deere, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), has provided the controlling framework for an obviousness analysis. A proper analysis under § 103(a) requires consideration of the four *Graham* factors of: determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims that are at issue; resolving the level of ordinary skill in the pertinent art; and evaluating any evidence of secondary considerations (e.g., commercial success; unexpected results). 383 U.S. at 17, 148 USPQ at 467. Here, the *Graham* factors reside in Appellants’ favor, including evaluation of any evidence of secondary considerations.

Moreover, it has been demonstrated – in the ‘Declaration under 37 CFR 1.132’ of Makoto Ishikawa, a copy of which appears in the Evidence Appendix – that the use of sucrose acetate isobutyrate as required by all of Appellants’ claims provides ***unexpected beneficial results***. The Examiner does not believe that the data presented in the Ishikawa Declaration is

commensurate in scope with Appellants' claims. The Examiner also does not believe that the data is sufficiently probative, due to such factors as the small sample of people used, the manner in which the data was reported, and the lack of establishment of qualifications for the testers. See the Advisory Action of February 21, 2008. Appellants make the following points with regard to the sufficiency of the comparative testing reported in the Ishikawa Declaration.

The Examiner refers to an allegedly small sample of people (testers) used. The testers, however, were selected from experienced personnel capable of high degrees of odor recognition, such that they can recognize odors of materials containing polyvalent unsaturated fatty acid components such as fish oils, animal oils, and vegetable oils. Moreover, these testers can identify emulsifier flavors sensitively. The testers employed have been active in evaluating various tests of flavors, and so they are quite suitable as testers in the present situation and thus 10 testers were used. Also, the number of the testers (10 testers) is not too few to conduct sensory evaluation tests. Accordingly, the testers used in the Ishikawa Declaration are appropriate to provide evidence of unexpected differences in properties in the present context.

In the claims, polyvalent unsaturated fatty acid components are recited. Accordingly, it is reasonable to use material containing a high level of those components, so that a typical material – fish oil – was used for the test. Fish oil is well known as a food material containing polyvalent unsaturated fatty acids, such as eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Accordingly, the use of fish oil in the testing is perfectly suitable.

Although glycerol is used in the testing, glycerol is not essential to the present invention. Glycerol is simply used to assist to disperse the hydrophilic emulsifier used in the test. Persons skilled in the art generally employ glycerol in such a test. However, without glycerol, the effects of the present invention are still exhibited. Accordingly, it is not problematic or a necessity that glycerol components are not recited in the claims.

The Examiner questioned the reporting of the evaluation criteria in the Ishikawa Declaration. That criteria was reported as follows: O = 0 to 2 individuals out of 10 recognize or slightly recognize fish odor; Δ = 3 to 5 individuals out of 10 recognize or slightly recognize fish odor; X = 6 to 10 individuals out of 10 recognize or slightly recognize fish odor. The underlying raw data was as follows:

<i>Raw Data</i>						
	Ex. 1	Ex. A	Ex. B	Ex. C	Ex. D	Control
Cow's milk	0	3	4	4	4	7
Yogurt drink	1	3	5	4	4	7
Orally taken liquid food	1	3	5	5	5	8

The Ishikawa Declaration contained the following Table:

Table II						
	Ex. 1 of Present Invention	Follow-up Ex. A	Follow-up Ex. B	Follow-up Ex. C	Follow-up Ex. D	Control
Commercially Available Cow's milk	O	Δ	Δ	Δ	Δ	X
Commercially Available Yogurt drink	O	Δ	Δ	Δ	Δ	X
Commercially Available Orally taken liquid food	O	Δ	Δ	Δ	Δ	X

Applicants respectfully submit that, based upon the current record, the rejection of claims 1-4 over the Sakurada and Yamada and Takahashi disclosures is not sustainable.

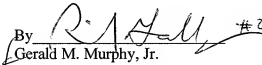
Contact information

If there are any questions concerning the present application, the Examiner and/or the Board is invited to contact Richard Gallagher (Registration No. 28,781) at (703) 205-8008.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Dated: March 13, 2009

Respectfully submitted,

By  #28,781
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(viii) CLAIMS APPENDIX.

1. An oil-in-water emulsion composition comprising
a fat or oil composition comprising a polyvalent unsaturated fatty acid component and sucrose acetate isobutyrate, wherein the amount of the sucrose acetate isobutyrate is from 25 to 300 parts by weight, based on 100 parts by weight of the polyvalent unsaturated fatty acid component and
a polyglycerol fatty acid ester.
2. The oil-in-water emulsion composition according to claim 1, wherein the polyvalent unsaturated fatty acid component is at least one member selected from the group consisting of polyvalent unsaturated fatty acids, salts of polyvalent unsaturated fatty acids and polyvalent unsaturated fatty acid esters.
3. The oil-in-water emulsion composition according to claim 2, wherein the polyvalent unsaturated fatty acid is at least one member selected from the group consisting of docosahexaenoic acid, docosapentaenoic acid, eicosapentaenoic acid and arachidonic acid.
4. A foodstuff comprising the oil-in-water emulsion composition as defined in any one of claims 1 to 3.

(ix) EVIDENCE APPENDIX.

The ‘Declaration under 37 CFR 1.132’ of Makoto Ishikawa, which was entered by the Examiner in connection with the Amendment of January 31, 2008, is relied upon in connection with this appeal.

Docket No.: 1422-0655PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Makoto ISHIKAWA et al.

Application No.: 10/518,926

Confirmation No.: 7260

Filed: December 23, 2004

Art Unit: 1712

For: OIL-IN-WATER EMULSION
COMPOSITION

Examiner: Kugel, Timothy J.

DECLARATION UNDER 37 CFR 1.132

MS AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Makoto ISHIKAWA, residing in Mie, Japan, hereby declares and states as follows:

1. That I am one of the co-inventors of U.S. Application Serial No. 10/518,926 filed on December 23, 2004, entitled OIL-IN-WATER EMULSION COMPOSITION. I am thoroughly familiar with the contents of said Application, its prosecution before the United States Patent and Trademark Office and the references cited therein.

2. That I am a graduate of University of the Ryukyus, Faculty of Agriculture and received a master's degree in the year 1994, majoring in bioscience and biotechnology.

3. That I have been employed in Taiyo Kagaku Co., Ltd. since 1994 and have been assigned to the Research Laboratories.

4. That I have been involved in the research and development of emulsified functional oils and fats formulation since 1999.

5. That the following experiments were conducted by myself or under my direct supervision and control in order to verify that sucrose acetate isobutyrate used in the present invention is clearly distinguishable in suppression of unpleasant fish odor from other sucrose fatty acid esters.

EXPERIMENTAL METHOD

Follow-up Examples A to D

[Preparation of Oil-in-Water Droplet Emulsion Compositions]

DHA emulsions were prepared in the same manner as in Example 1 of the present invention except that the sucrose acetate isobutyrate of Example 1 was replaced with a sucrose fatty acid ester A, B, C, or D, each having HLB of 1.0 in the following formulations shown in Table I.

Table I

Raw Materials	
22% DHA-Containing Purified Fish Oil	280 g
Sucrose Fatty Acid Ester (Each of Follow-up Ex. A to D)*	120 g
Vegetable Oil	30 g
Glycerol	320 g
Pentaglycerol Dimyristate	30 g
Pentaglycerol Dioleate	30 g
Ion-Exchanged Water	180 g

*Sucrose Fatty Acid Ester

Follow-up Example A: Sucrose Stearate Ester (HLB: 1.0)

Follow-up Example B: Sucrose Palmitate Ester (HLB: 1.0)

Follow-up Example C: Sucrose Oleate Ester (HLB: 1.0)

Follow-up Example D: Sucrose Laurate Ester (HLB: 1.0)

Oil-in-water droplet emulsion compositions having the formulations as shown in Table I were prepared in the same manner as in Example 1 of the present invention. Each of the resulting oil-in-water droplet emulsion compositions was added to a commercially available drink in the same manner as in Test Examples of the present invention. The resulting emulsion-containing drinks were compared with that used with the emulsion composition of Example 1 of the present invention. In addition, as a control, only DHA-containing purified fish oil was added to a commercially available drink.

[Evaluation Methods]

(1) Commercially Available Cow's Milk (MEGMILK)

Fifty grams of each of the prepared composition was added to 950 g of a commercially available cow's milk, and the mixture was homogeneously mixed. The resulting mixture was warmed to 50°C, and a sensory test was conducted by 10 panelists. As a result, the number of panelists who did not strongly recognize fish odor in the case

where the emulsion composition of Example 1 is used was large as compared to that of each of Follow-up Examples A to D. The results are shown in Table II.

(2) Commercially Available Yogurt Drink (Meiji Bulgaria Drinking Yogurt LB81 Plain)

Fifty grams of each of the prepared composition was added to 950 g of a commercially available yogurt drink, and the mixture was homogenously mixed. The resulting mixture was warmed to 40°C, and a sensory test was conducted by 10 panelists. As a result, the number of panelists who did not strongly recognize fish odor in the case where the emulsion composition of Example 1 is used was large as compared to that of each of Follow-up Examples A to D. The results are shown in Table II.

(3) Commercially Available Orally Taken Liquid Food (Meibalance 200 Vanilla)

Fifty grams of each of the prepared composition was added to 950 g of a commercially available orally taken liquid food, and the mixture was homogenously mixed. The resulting mixture was warmed to 40°C, and a sensory test was conducted by 10 panelists. As a result, the number of panelists who did not strongly recognize fish odor in the case where the emulsion composition of Example 1 is used was large as compared to that of each of Follow-up Examples A to D. The results are shown in Table II.

[Evaluation Criteria]

- : 0 to 2 individuals out of 10 recognize or slightly recognize fish odor.
- △: 3 to 5 individuals out of 10 recognize or slightly recognize fish odor.
- ×: 6 to 10 individuals out of 10 recognize or slightly recognize fish odor.

RESULTS AND DISCUSSION

Table II

	Ex. 1 of Present Invention	Follow-up Ex. A	Follow-up Ex. B	Follow-up Ex. C	Follow-up Ex. D	Control
Commercially Available Cow's Milk	○	△	△	△	△	×
Commercially Available Yogurt Drink	○	△	△	△	△	×
Commercially Available Orally Taken Liquid Food	○	△	△	△	△	×

It can be seen from the above test results that among sucrose fatty acid esters, only sucrose acetate isobutyrate used in Example 1 of the present invention remarkably exhibits an action of suppressing unpleasant fish odor. This action is specific to sucrose acetate isobutyrate, not found in other sucrose fatty acid esters.

Statement Under 18 U.S.C. § 1001

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: *January 23rd, 2008* By: *M. Ishikawa*

Makoto ISHIKAWA

(x) RELATED PROCEEDINGS APPENDIX.

There are no related proceedings (none).